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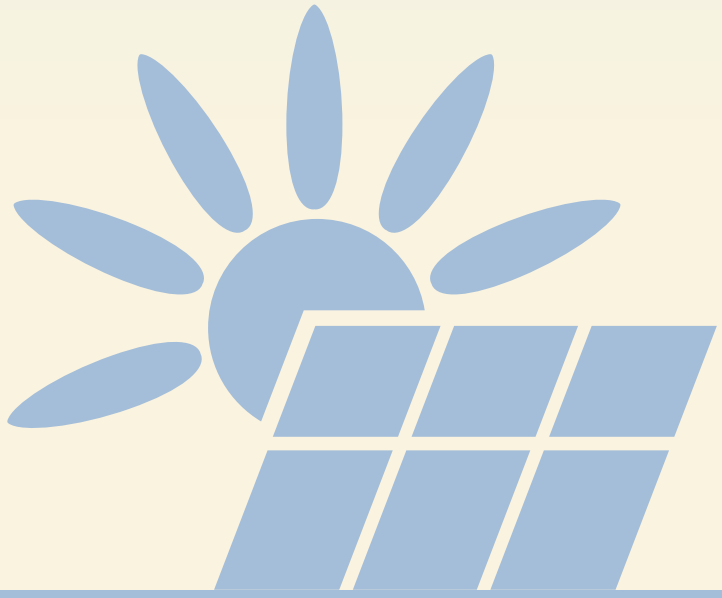
Life PHARMA DETOX

Demonstration of an innovative method for the detoxification of pharmaceutical wastewater from pharmaceutical facilities

Layman's Report



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Demonstration of an innovative method for the detoxification of pharmaceutical wastewater from pharmaceutical facilities

PHARMADETOX in a nutsell

LIFE PHARMA-DETOX "Demonstration of an innovative method for the detoxification of pharmaceutical wastewater from pharmaceutical facilities", is a project funded by EU LIFE Programme. It is coordinated by Medochemie and delivered by a consortium of leading industrial, academic and SME partners, including the National Technical University of Athens (UEST), the University of Catania, Nevis Environmental Solutions S.A., and Aarhus University, combining complementary expertise in pharmaceutical manufacturing, environmental engineering, advanced wastewater treatment, communication and dissemination as well business exploitation.

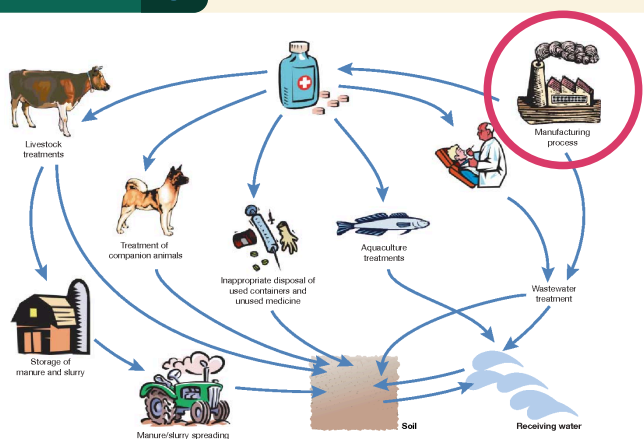
The project developed, implemented and tested an innovative, economically viable and cost-efficient system for the transformation of pharmaceutical compounds, present in wastewater, into non-toxic substances (novel detoxification process).

The system is able to treat the wastewater generated from production activities, ensuring that no APIs would end up in the wastewater sewage system without being processed and detoxified by the system developed.

The strong technical performance demonstrated by LIFE PHARMA-DETOX has paved the way for the patenting of its innovative catalytic hydrogenation process, including the proprietary catalyst, gas mixture, and optimized operating conditions. Beyond technology validation, the project has established a comprehensive framework for transferability, replicability, and market uptake through a dedicated business exploitation roadmap outlining future commercialization opportunities and pathways for wider deployment.

Environmental Issues Addressed by the Project

Active Pharmaceutical Ingredients (APIs) represent one of the most significant challenges in pharmaceutical wastewater treatment. These bioactive compounds, essential for drug production, can have significant environmental impacts when released into surface waters, even in minimal concentrations. APIs are substances responsible for the therapeutic effect of drugs. Designed to interact with specific biological targets in humans and animals, these compounds maintain their biological activity even after being released



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into the environment. When they reach aquatic ecosystems through industrial wastewater, they can cause harmful effects on aquatic flora and fauna, alter ecosystem balances, and contribute to the worrying phenomenon of antibiotic resistance act as endocrine disruptors, and cause long-term chronic toxicity to aquatic life.

The bioaccumultation of **APIs (Active Pharmaceutical Ingredients)** can lead to:

- The potential induction of antimicrobial resistance in microorganisms.
- The exhibition of endocrine-disrupting properties.
- Long-term negative impacts on aquatic life due to chronic toxicity.

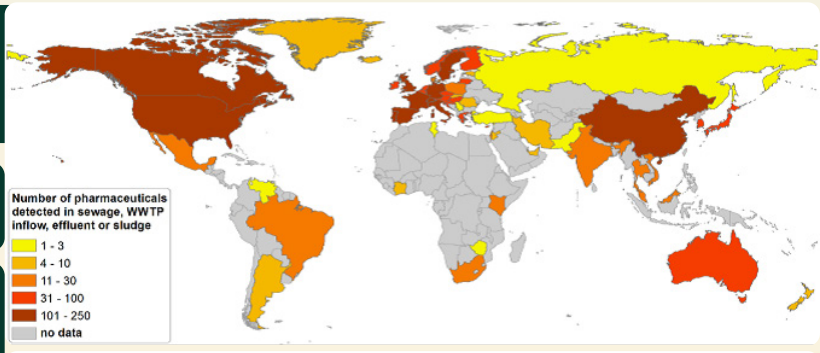
Globally, over 80% of the wastewater generated by pharmaceutical industry operations is discharged untreated, and residue hotspots near manufacturing sites are linked to antimicrobial resistance (AMR) — listed by the World Health Organization as one of the top ten global public health threats.

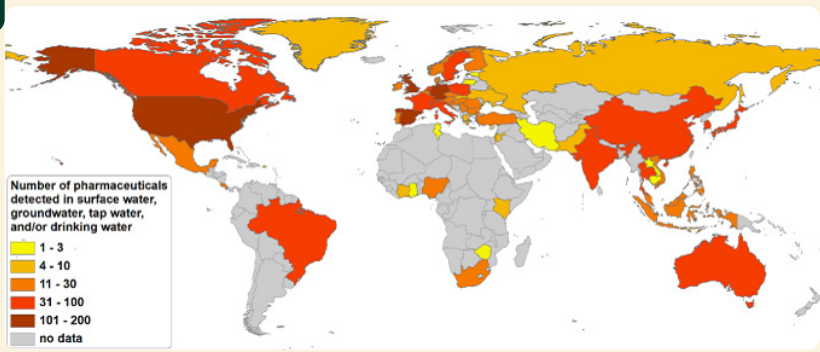
92% of residual toxicity in urban wastewater comes from the pharmaceutical and cosmetics sectors (Europe's state of water 2024)

Pharmaceuticals in the environment

559 different pharmaceuticals have been detected globally

100 different pharmaceutical substances found in several European countries and the USA





Pharmaceuticals in the environment: Global occurrence and potential cooperative action under the Strategic Approach to International Chemicals Management (SAICM), from T. aus der Beek, F.-A. Weber, A. Bergmann, S. Hickmann, I. Ebert, A. Hein, and A. Küster, 2019, Umweltbundesamt.

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Challenges for the Pharmaceutical Industries

01 **No universal technology exists**

No single commercially available technology removes all pharmaceutical compound classes from manufacturing wastewater

02 **Costs are far higher than regulators estimated**

Germany's Environment Agency: quaternary treatment costs €885–1,025 million/year — four times the European Commission's figure of €238 million

03 **Regulatory uncertainty, but obligation is now confirmed**

Industry warned of potential medicine shortages and market withdrawals in some countries

04 **Good Manufacturing Practice (GMP) regulations impose strict quality standards on all water used in production and equipment cleaning**

05 **Multi-API complexity**

Medochemie operates 13 manufacturing sites with different product lines, different API profiles, and different wastewater volumes

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General Objectives

Aims το:

- Detoxify wastewater from pharmaceutical industry and avoid APIs release in the wastewater sewage system.
- Promote the circular economy concept for pharmaceutical industry by the recovery of water that would otherwise have been discharged in the wastewater sewage system.

Achieved through:

- Development and implementation of an innovative and cost-efficient system for the transformation of pharmaceutical compounds in wastewater, into non-toxic substances.
- Use of recovered water in noncritical applications (heat exchanging systems, cleaning, irrigation).

Specific Objectives & KPIs

- **Avoid** Active Pharmaceutical Ingredients (APIs) release in the wastewater sewage system.
- **Convert** 1,606 kg of APIs to nontoxic compounds
- **Save** 913 m^3 of potable water annually.
- **Reuse and Recycle** clean water for manufacturing plants or used of irrigation purposes.
- **Minimize** the system's environmental footprint through the use of 100% renewable energy sources.
- **Transfer** the project's results to other pharmaceutical companies across Europe.
- **Communicate and promote** public awareness at the local and regional level, including authorities, universities, and pharmaceutical manufacturing industries.
- **Draft policy recommendations to the EU.**
- **Create** an effective value chain through the socio-economic impact of the proposed actions.

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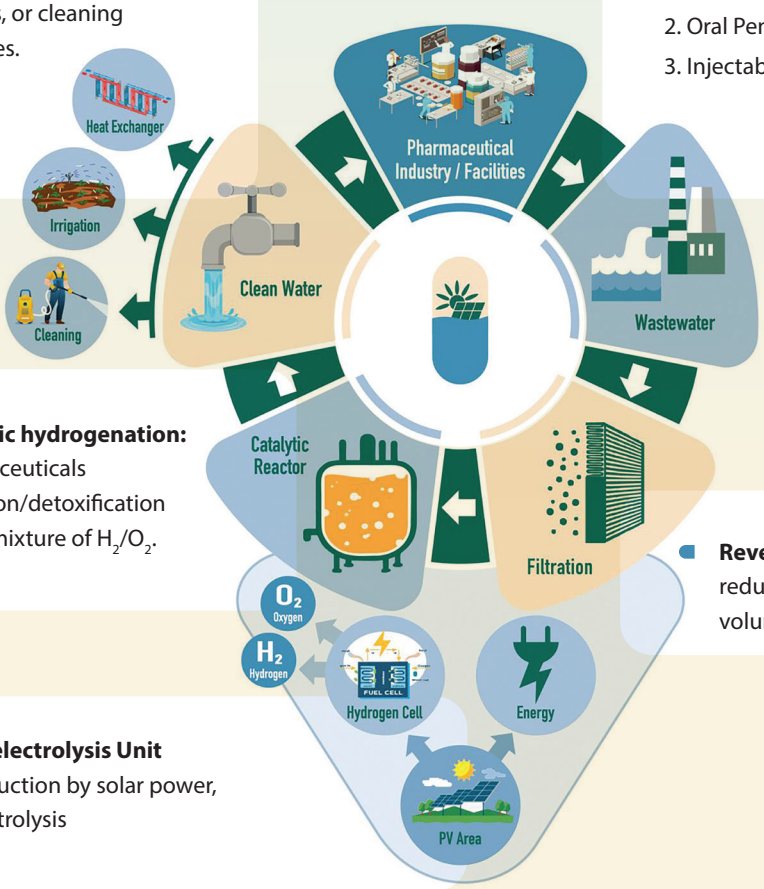
Process – Pilot System

Wastewater from the pharmaceutical facility passes through filtration, then a catalytic reactor (supplied with hydrogen produced on-site by an electrolysis unit powered by solar PV) breaks down the pharmaceutical compounds into non-toxic substances. The clean water recovered at the end of the process is reused for non-critical purposes such as heat exchange, cleaning and irrigation, closing the loop on water use at the site.

- **Two streams** of recovered water can be used for irrigation, heat exchanging systems, or cleaning purposes.

- **Wastewater produced** during the equipment cleaning:
  1. Ampoule Injectable Facility
  2. Oral Penicillin Facility
  3. Injectable Penicillin Facility



- **Catalytic hydrogenation:** Pharmaceuticals reduction/detoxification with a mixture of H_2/O_2.

- **Reverse Osmosis:** 80-90% reduction of wastewater volume

- **Water electrolysis Unit**
  H_2 Production by solar power, PV-electrolysis

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Wastewater Origin

Ampoules Injectable Facility Line 1 and 2

Injectable Penicillin Facility

Oral Penicillin Facility

Water from rinsing equipment and filters, this solution contains laboratory detergent

Water from washing lab clothes in washing machines, this solution contains laundry detergent

Monitoring Points

Permeate Tank

- APIs Concentration
- Acute Toxicity to microorganisms
- Toxicity to plants
- TSS, Turbidity, COD, Conductivity, E. coli, BOD

Water for irrigation

- APIs Concentration
- Acute Toxicity to microorganisms
- Toxicity to plants
- TSS, Turbidity, COD, Conductivity

Buffer and Coagulation Tank

RO

Water for cleaning purposes

- APIs Concentration
- Acute Toxicity to microorganisms
- Toxicity to plants
- Turbidity

Concentrate Tank

- APIs Concentration
- Turbidity

Catalytic Reactor

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Implementation

1st Demonstration Phase in Limassol, Cyprus

The initial installation of the pilot wastewater treatment unit was completed at Medochemie's premises in Limassol, Cyprus.

The pilot system is fully containerized and divided in two functional areas. The reverse osmosis unit which removes physically organic molecules and inorganic ions is installed in the first area. The second area holds the catalytic reactor and the water-electrolysis system that supplies it with hydrogen.

This second area is built to ATEX specifications for safe operation in the presence of hydrogen gas.

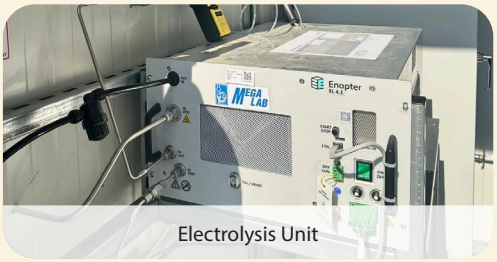
The system ran under real industrial conditions, and this experimental work enabled the team to define its optimal operating parameters. The main active pharmaceutical ingredient (API) treated during this phase was amoxicillin.

The Pharma Detox System-Limassol


Buffer Coagulation Tank


RO Unit


Catalytic Reactor



Electrolysis Unit


PV Area

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The Pharma Detox System

Container

Non-Atex Zone

Atex Zone

SAFETY FIRST

Non-ATEX Zone

Reverse Osmosis (RO) unit safe area for membrane-based pre-treatment and water recovery

ATEX Zone II

Catalytic reactor, electrolysis unit, and H_2 gas cylinders, classified hazardous area **with explosion** safety compliance.

Implementation

2nd Demonstration Phase in Duiven, the Netherlands

Following the completion of experimental work done in Limassol, the LIFE PHARMA-DETOX system was transferred to FALDV in Duiven, Netherlands. After its installation and connection to the pharmaceutical plant the pilot system operated under the conditions of the host pharmaceutical site, which allowed the tests to cover different operating conditions, additional groups of APIs, and wastewater streams with different synthesis routes from those tested in Limassol. The results confirm the robustness of the system and its ability to adapt to different operating conditions, wastewater compositions, and API groups.

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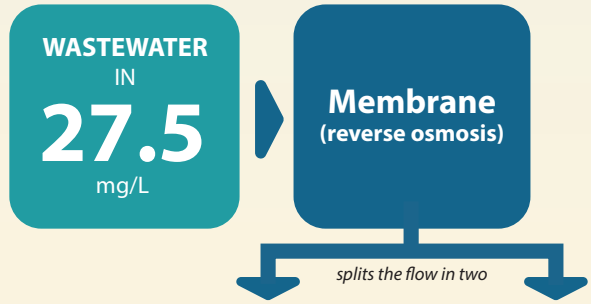
Pilot system operation results

Methodology used for water safety tests

01	02	03
Drug residue	**Toxicity test**	**Phytotoxicity**
Exact measurement of pharmaceutical residue from every stage.	Daphnia magna was used to test water purity.	Three different plants were used to test the water quality.
Laboratory method: HPLC	*International standard ISO 6341*	*International standard ISO 18763*

Two streams used

The membrane splits the wastewater in two. Each stream is then cleaned in its own way.



Both figures clear the legal bar.
The EU Urban Wastewater Treatment Directive (2024/3019) requires at least 80% removal. The membrane reaches 88%, and the catalytic reactor 97% — rising above 99% in the best runs.

STREAM 1 — **TREATED BY RO STREAM**

88% **less drug residue**
27.5 → 3.3 mg/L • held out by the membrane
Reused for crop irrigation

STREAM 2 — **TREATED IN THE CATALYTIC REACTOR**

KEY RESULT

98% **less drug residue**
64.0 → 1.9 mg/L • broken down
Reused on site for cleaning

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Results

Both streams were tested on living organisms, using internationally standardised methods.

STREAM 1 — **TREATED BY RO STREAM**

Water fleas *Daphnia magna*
Non-toxic
Acute Toxicity according to ISO 6341

Plants *three species*
No harmful effect
Phytotoxicity test based on ISO 18763

Confirmed safe to reuse and to discharge.

STREAM 2 — **TREATED IN THE CATALYTIC REACTOR**

Water fleas *Daphnia magna*
Up to 90% less toxic
Acute Toxicity according to ISO 6341

Plants *three species*
Up to 85% less toxic
Phytotoxicity test based on ISO 18763

What is left approaches the lowest level the tests can detect.

Environmental and socio-economic benefits

Environmental benefits

Cleaner rivers and ecosystems
Reduces pharmaceutical residues and toxicity before discharge.

Water recovered for reuse
Treated water can be reused for irrigation, cleaning and cooling.

Less pressure on freshwater resources
Water reuse helps save valuable potable water.

Renewable-powered treatment
The system uses photovoltaic electricity and renewable hydrogen production.

Circular use of resources
Turns wastewater into a resource and supports a circular economy.

Socio-economic benefits

Lower water demand and costs
Reusing water can reduce freshwater consumption and related operating costs.

Better regulatory preparedness
Helps companies respond to stricter environmental requirements.

Reduced environmental risk
Lower pollutant discharge can reduce compliance and reputational risks.

Replicable European solution
A modular concept can be adapted to other pharmaceutical facilities.

Innovation and skilled jobs
Supports expertise in water treatment, renewable energy and monitoring.

Better Management of AMR

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EU regulatory landscape

Why the rules are changing

For decades, European wastewater legislation contained limited provisions addressing pharmaceutical residues. LIFE PHARMA-DETOX was launched to address this regulatory gap by demonstrating an innovative solution for the treatment of pharmaceutical wastewater at source. During the project's implementation, the regulatory landscape evolved significantly. In 2024, the European Union adopted the revised Urban Wastewater Treatment Directive, introducing, for the first time, mandatory requirements for the removal of pharmaceutical residues from wastewater.

This new regulatory framework has three major implications:

The polluter pays principle: it reinforces the "polluter pays" principle, requiring pharmaceutical and cosmetics producers to finance at least 80% of the costs associated with the additional treatment needed to remove micropollutants.

There is a deadline: it establishes a clear implementation timeline, with larger urban wastewater treatment plants required to progressively introduce advanced treatment technologies by 2045.

Openness is expected: it significantly strengthens corporate transparency by requiring large companies to publicly report on their water management and pollution performance, while the pharmaceutical industry is also advancing sector-specific wastewater discharge standards.

The impact of this legislation extends beyond pharmaceutical manufacturers to any industrial sector whose activities release pharmaceutical substances or comparable micropollutants into aquatic environments. In this context, treating wastewater at its source, before contaminants enter public sewer systems, represents the most effective, sustainable and economically efficient approach. This is precisely the solution demonstrated by LIFE PHARMA-DETOX, providing industry with a practical pathway to meet emerging regulatory requirements while protecting water resources and supporting Europe's transition towards a cleaner and more sustainable future.

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Replication and Transferability

LIFE PHARMA-DETOX is designed as a modular, containerised, on-site treatment system that can be installed in existing facilities without major changes to their production processes. Its flexible design allows the system to be adapted to different wastewater volumes, production lines and pharmaceutical compounds.

The system has already been transferred to FAL Duiven B.V. in Duiven, the Netherlands, where it was installed and operated in a different industrial environment. This successful transfer demonstrates that the technology can be transported, integrated and operated beyond the original demonstration site.

PHARMA-DETOX has also been tested on wastewater containing different groups of active pharmaceutical ingredients, confirming that the treatment concept is not limited to a single API, pharmaceutical group or production line.

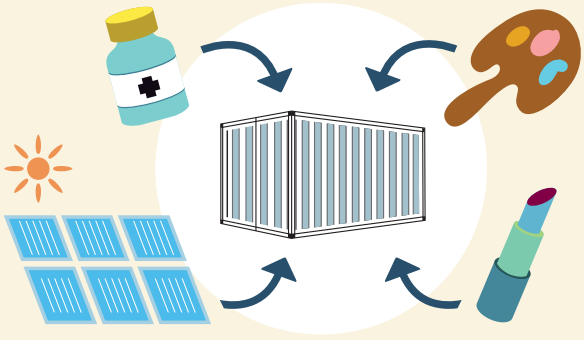
In parallel, replication feasibility studies are being carried out in Greece and Italy. These activities assess wastewater characteristics, technical requirements, design parameters and expected implementation costs for applying the system in additional pharmaceutical facilities.

Its modular design allows adaptation to different wastewater characteristics, treatment capacities and production settings, including:

- API synthesis facilities;
- antibiotic and penicillin formulation plants;
- sterile injectable production;
- pharmaceutical laboratories and formulation facilities;
- contract manufacturing organisations.

Beyond pharmaceutical manufacturing, the technology also has transferability potential for hospitals, healthcare facilities and urban wastewater-treatment plants, where it could be applied as an additional advanced treatment stage for pharmaceutical residues and other persistent organic compounds.

The core catalytic process is under patent preparation, supporting future replication, licensing and commercial deployment



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After LIFE activities scheduled

After the end of the LIFE PHARMA-DETOX project, the pilot system will remain installed and in operation at Medochemie's premises, run by the company's own personnel. Medochemie is also considering installing similar units at other manufacturing facilities outside Cyprus. The company will continue to promote and showcase the system to the wider pharmaceutical sector and plans to publish further performance results once the patent application for the core catalytic hydrogenation process has been granted.

- The project website will be active for 5 more years after the project end, to provide the website visitors full access in all the project information, activities, and results. The website will also include the research papers and technical publications from the project work to highlight its outcomes and achievements in the scientific community
- The notice board of the project will remain at the premises of the partners for 2 more years after the project end. Therefore, a concise overview of the project concept outlining that the innovative system not just treats wastewater, but creates value from it, will be visible to a broad network of institutes, universities, and industries that the project partners have cultivated.
- A working group will be constituted from project partners to disseminate the project results and foster connections with representatives from pharmaceutical sector across Europe.
- LIFE PHARMA-DETOX results & accomplishments will be presented in relevant Conferences & events on wastewater treatment and/or other events related to pharmaceutical or industrial activities related to APIs conferences (i.e the International Conference on Sustainable Solid Waste Management, also organized by NTUA).

COORDINATING BENEFICIARY

MEDOCHEMIE

ASSOCIATED BENEFICIARIES

AARHUS UNIVERSITY

NEVIS

UNIVERSITÀ degli STUDI di CATANIA

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